K112176

5- 510(k) Summary

SEP 15 2011

OCULOPLASTIK

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July 26th, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

RE: Premarket notification modification – Special 510(k)

Device name:	Silicone Eye sphere implants
Regulation number:	21 CFR 886.3320
Regulatory Class:	Class II
Product code:	HPZ
Establishment reg:	8022166
Contact person:	Sylvain Desrosiers, QM (514)381-3292 sdesrosiers@oculoplastik.com

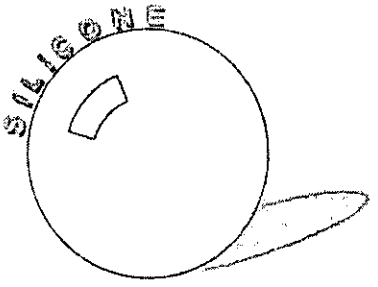
This is a submission for a special 510(k) for our Silicone Eye sphere implants, which were previously cleared by FDA in 2004 (K040689). The basis for this submission is change of material grade and supplier, as the resin's manufacturer is discontinuing the current silicone grade. There is also a change for labeling and packaging. According to guidance "Deciding When to submit a 510(k) for a Change to an Existing Device" (CDRH, 1997), we determined that this change must be submitted to FDA prior to market in USA (paragraph C3).

This material change does not affect the intended use, and does not alter the fundamental scientific technology of the device, therefore we are eligible to Special 510(k) approach.

We have determined that both silicone elastomers are equivalent and do not represent additional risk for the user.

Description of the device

Intended use



Silicone eye sphere implants are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or the space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and possibly, given the surgical method, to impart motion to the eventual ocular prosthesis.

Silicone eye spheres have been used for decades and still are. As for any implant, spheres are single use. Users are ophthalmologists who are very qualified to use eye spheres. Furthermore, we provide instructions for use with each device. These instructions include:

- Description
- Appearance
- Indications
- Silicone sphere
- Mode of action
- Contra-indications
- Adverse effects
- Recommendation for use
- Precautions for use

They are available by units in a wide range of sizes, from 12 to 22mm.

Radius	Vol.	Weight	Product no
12mm	0.9cc	1.0 g	11-212E
13mm	1.2cc	1.3 g	11-213E
14mm	1.4cc	1.7 g	11-214E
15mm	1.8cc	2.0 g	11-215E
16mm	2.1cc	2.5 g	11-216E
17mm	2.6cc	3.0 g	11-217E
18mm	3.1cc	3.5 g	11-218E
19mm	3.6cc	4.1 g	11-219E
20mm	4.2cc	4.8 g	11-220E
21mm	4.8cc	5.6 g	11-221E
22mm	5.6cc	6.4 g	11-222E

Intended use

Intended use

Silicone eye sphere implants are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac

(evisceration), or the space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and possibly, given the surgical method, to impart motion to the eventual ocular prosthesis.

The new device is substantially equivalent to the predicate device. The comparison is established against our previous 510(k). The following comparison table shows similarities and differences between both devices.

	Predicate device	**New device**
510(k) number	K040689	K112176
FDA Product Class	Class II	Same.
Indications for use	For enucleation, evisceration, or as secondary implant.	Same.
Target population	All ages.	Same.
Design	Silicone elastomer Eye Sphere	Same.
Material	Medical grade	Medical too but different grade
Performance	No performance standards applicable to SPHERE, EYE IMPLANT has been assigned by FDA.	Same.
Size Range	12, 13, 14, 15, 16, 17, 18 and 19mm	12 to 22mm
Sterility	Non sterile.	Same. Must be sterilized by steam autoclave by the user.
Biocompatibility	The silicone manufacturer has done many biocompatibility tests on their resin.	Equivalent. The silicone manufacturer has done same biocompatibility tests with same results. In addition, we have performed 2 other tests on finished device.
Mechanical safety	Silicone in its solid state is well documented by manufacturers of silicon resins, and well known by ophthalmologists.	Same.
Chemical safety	Silicone is an inert material.	Same.
Anatomical sites	Ocular globe replacement or filling.	Same.
Human factors	Users are ophthalmologists.	Same.

Energy used and/or delivered	No energy involved for this type of procedure.	Same.
Compatibility with environment and other devices	In use for decades.	Same.
Where used	Operating rooms in hospitals.	Same.
Standards met	None.	ISO 14971
Electrical safety	No electricity involved for this type of procedure.	Same.
Thermal safety	Can be autoclaved or gassed (ETO)	Same. Highly resistant.
Radiation safety	No radiation involved for this type of procedure.	Same.
Color additives	Non applicable. No color additives used in the manufacturing process.	Same.
Software	Non applicable. No software involved for this device.	Same.

No performance standards applicable to SPHERE, EYE IMPLANT has been assigned by FDA. However, a risk assessment has been performed against ISO 14971.

Sterility

Silicone spheres are sold «Non Sterile». The labels clearly mention that they are not sterilized. Sterilization of these implants is required before surgery.

Pyrogens

Non applicable. These devices are labeled as non-sterile and need to be sterilized by the user.

Sterilization by User

The standard accepted sterilization method is to be performed in the hospitals that will purchase the implants. We provide detailed validated steam sterilization instructions in our labeling for the silicone spheres.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Oculo –Plastik, Inc.
c/o Mr. Sylvain Desrosiers
Quality Manager
200 rue Sauvé ouest
Montreal, Quebec H3L 1Y9
Canada

Re: K112176
Trade/Device Name: Silicone Spheres
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye Sphere Implant
Regulatory Class: Class II
Product Code: HPZ
Dated: August 25, 2011
Received: September 6, 2011

SEP 15 2011

Dear Mr. Derosiers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kezia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K112176

4- Indication for use statement

510(k) Number (if known):

Device Name: Silicone Eye Sphere Implants

Indication for use

Silicone eye sphere implants are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or the space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and possibly, given the surgical method, to impart motion to the eventual ocular prosthesis.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise Hampton

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112176